DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 25 2011

Re: Actemra
Patent Nos. 5,670,373; 5,795,965; 5,888,510
Docket Nos.: FDA-2010-E-0328
FDA-2010-E-0324
FDA-2010-E-0325

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,670,373 and 5,795,965, filed by Chugai Seiyaku Kabushiki Kaisha, and for U.S. Patent No. 5,888,510, filed by Chugai Seiyaku Kabushiki Kaisha and Tadamitsu Kishimoto, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Actemra (tocilizumab), the human biological product claimed by the patents.

The total length of the regulatory review period for Actemra is 1,893 days. Of this time, 1,111 days occurred during the testing phase and 782 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: November 4, 2004.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 4, 2004.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: November 19, 2007.

   FDA has verified the applicant's claim that the biologics license application (BLA) for Actemra (BLA 125276/0) was initially submitted on November 19, 2007.

3. The date the application was approved: January 8, 2010.

   FDA has verified the applicant's claim that BLA 125276/0 was approved on January 8, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Stephen B. Maebius
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